CLAIMS

1. Controlled release formulations containing melatonin, characterized by being made from an interior slow release nucleus and from an exterior fast release "cortex", both containing melatonin in equal or different doses.
2. Formulations according to claim 1, characterized by the fact that the melatonin content may be between 0.1 and 100mg either in the interior nucleus or in the exterior "cortex".
3. Formulations according to claim 2, characterized by the fact that the fast release "cortex" contains the active ingredient preferably in a quantity of 1 mg and the slow release nucleus contains the main ingredient preferably in a quantity between 0.5 and 3 mg (inclusive).
4. Process for the preparation of controlled release formulations characterized by the fact that an interior nucleus and an exterior "cortex" must be prepared , both containing an active ingredient capable of releasing the active ingredient biphasically and, in particular, characterized by the following stages: a) preparation of the delayed-release nucleus containing the active ingredient; b) formation of the "cortex" containing the active ingredient, under control; c) fixation of the said "cortex".
5. Process according to claim 4, characterized by the fact that the formulations are the formulations in claim 1.
6. Process according to claims 4, characterised by the fact that stage a) consists of:

- preparation of the active ingredient mixture, to make the slow release nucleuss, with volume excipients, gliding and lubricating excipients, binding excipients and retardant excipients; preparation of slow release nucleuss.

7. Process according to claim 6, in which the preparation of the interior nucleuss containing the active ingredient, the volume excipients, gliding and lubrication excipients, binding excipients and retardant excipients can be calcium phosphate, mannitol, lactose, aerosyl, magnesium stearate, polyvinylpyrrolidin and hydroxypropylmethylcellulose;
8. Process according to claim 6, characterized by the fact that the preparation of the interior nucleus consists of:

- granulation
- calibration of the granulation
- controlled pressure compression

9. Process according to claim 8, characterized by the fact that nuclei with preferable hardness of 7-8 kN are obtained;

10. Process according to claims 4, characterised by the fact that stage b) consists of:

- preparation of the solution containing the active ingredient;
- application of the solution under pressure.

11. Process according to claim 10, characterized by the fact that for the preparation of the active ingredient solution the preferred excipients may be chosen from hydroxypropylmethylcellulose, lactose, ethyl alcohol, purified water.

12. Process according to claim 11, characterized by application of a solution of the active ingredient under pressure under control on the quantity of the active ingredient by means of chemical analysis carried out on samples taken during application.

13. Use of the formulations according to claim 1 for the preparation of drugs for the treatment of sleep disorders.

14. Use of the formulations according to claim 1 for the preparation of nutritional supplements or foods for the treatment of or as coadjutants in the treatment ofsleep disorders.

15. Use of the formulations according to claim 1 to substitute the decreased melatonin levels.